NDA 19-906/S-009

Tyco Healthcare Group LP
Attention: Ms. Marianne Robb
Manager, Regulatory Submissions
15 Hampshire Street
Mansfield, MA 02048

31 JUL 2001

Dear Ms. Robb:

Please refer to your supplemental new drug application dated July 30, 1991, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Anafranil (clomipramine hydrochloride) 25 mg, 50 mg, and 75 mg Capsules.

We additionally refer to an Agency approvable letter dated November 7, 2000 for the above supplemental application.

We acknowledge receipt of your submission dated May 15, 2001, providing for a response to our November 7, 2000, Agency letter.

This supplemental new drug application provides for revisions to the **PRECAUTIONS-Carcinogenesis, Mutagenesis, Impairment of Fertility**, **PRECAUTIONS-Pregnancy Category C**, and the **ANIMAL TOXICOLOGY** sections of labeling.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted May 15, 2001/Label Code T2001-39/#89000602), which incorporates all of the revisions listed. Accordingly, this supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Mr. Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

Sincerely,

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research